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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC., Plaintiffs, v. ANCHEN PHARMACEUTICALS, INC. Defendant.	Civ. No. 11-cv-06348-JAP-(DEA) (Consolidated for discovery purposes with Civ. No. 11-cv-02317-JAP-DEA and Civ. No. 11-cv-04275-JAP-DEA)

ANCHEN'S OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

Defendant Anchen Pharmaceuticals, Inc. ("Anchen") submits this brief in support of its constructions for the disputed claim terms of U.S. Patent No. 6,926,907 ("the '907 patent"), U.S. Patent No. 6,369,085 ("the '085 patent"), U.S. Patent No. 7,411,070 ("the '070 patent"), and U.S. Patent No. 7,745,466 ("the '466 patent"). Anchen's constructions are consistent with the meaning of these terms, as informed by the descriptive portion of the specification and the prosecution history, and so should be adopted.

In cases Civ. No. 11-cv-02317-JAP-DEA and Civ. No. 11-cv-04275-JAP-DEA, since consolidated with the present case for discovery (the "Consolidated Cases"), Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (together "DRL"), and Lupin Ltd. and Lupin Pharmaceuticals Inc. (together "Lupin") jointly filed a brief titled "Defendants' Opening Claim Construction Brief" on May 9, 2012 (D.I. 68, the "DRL/Lupin Brief"). As specifically indicated *infra*, Anchen adopts certain portions of the DRL/Lupin Brief addressing certain claim terms in the patents listed above. Anchen's claim construction brief generally focuses on disputed claim terms not addressed in the DRL/Lupin Brief.

II. BACKGROUND

Anchen adopts the Background section of the DRL/Lupin Brief with the following additional comments.

Three of the four patents at issue in the present case, the '085, '070 and '466 patents (the "trihydrate patents") relate to esomeprazole magnesium trihydrate. Asserted claims 5, 15 and 52–54 of the remaining patent, the '907 patent, relate to a unit dosage form which contains a combination of two old drugs, a nonsteroidal anti-inflammatory drug (an "NSAID") and a proton pump inhibitor (a "PPI"), where the unit dosage form provides for "coordinated release" of the two drugs. The Court's construction of the term "coordinated

release" is central to the present parties' dispute over the breadth of the '907 patent.[1] Anchen's construction of this term is consistent with the intrinsic record, where the patentee touted this feature as differentiating the asserted invention from the prior art. Plaintiffs, on the other hand, propose equating "coordinated release" with the simple concept of "sequential release," which is inconsistent with the intrinsic record. Because Anchen's proposed constructions of this term, as well as the others, are better grounded in the intrinsic record, the Court should adopt Anchen's constructions.

III. ARGUMENT

A. Legal Standards for Claim Construction

Anchen adopts the "Legal Standards for Claim Construction" section of the DRL/Lupin Brief with the following additional comments.

In *Phillips v. AWH Corp.*, the Federal Circuit described the methodology for construing the claim terms of a patent. *See Phillips*, 415 F.3d 1303, 1314–19 (Fed. Cir. 2005) (en banc). To construe a claim term, a court must first examine the "intrinsic evidence": the language of the claims, the descriptive portion of the specification, and the prosecution history. *Id.* at 1313. Unless an examination of the intrinsic evidence shows that the patentee acted as his own lexicographer in writing a claim term, or used a claim term in an idiosyncratic way, the claim term is given its "ordinary and customary meaning . . . [as] the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.*

[1] The parties also dispute the construction of the phrase "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon administration of one or more of said unit dosage forms," along with several additional terms also disputed in the Consolidated Cases.

The claims "must be read in view of the specification, of which they are a part." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996)). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* The prosecution history is also relevant to claim construction. *See Desper Prods. Inc. v. QSound Labs, Inc.*, 157 F.3d 1325, 1336–37 (Fed. Cir. 1998) ("Prosecution history is an important source of intrinsic evidence in interpreting claims because it is a contemporaneous exchange between the applicant and the examiner.").

B. U.S. Patent No. 6,926,907

Anchen adopts the section of the DRL/Lupin Brief addressing the '907 patent with the following additional claim terms and arguments.

The disputed terms of the '907 patent are found in claim 1. While Plaintiffs are not asserting claim 1 of the '907 patent against Anchen, asserted claims 5, 15, and 52–54 all depend, directly or indirectly, from claim 1.

The '907 patent generally is directed to the co-administration of two old drugs: (1) an NSAID for pain relief; and (2) an acid inhibitor to reduce the well-known gastrointestinal side effects associated with NSAID administration. *See* '907 patent at 1:11–18. More specifically, claim 1 is directed to a unit dosage form which contains a combination of an NSAID and an acid inhibitor[2] present in an amount effective to raise gastric pH to at least 3.5, where the unit dosage form provides for "coordinated release" of the two drugs. The '907 patent discloses that "[t]he term 'acid inhibitor' refers to agents that inhibit gastric acid

[2] Asserted claim 5, from which asserted claims 15 and 52–54 directly or indirectly depend, limits the acid inhibitor to a select group of well-known PPIs including omeprazole.

secretion and increase gastric pH," and includes well-known H2 blockers such as famotidine and PPIs such as omeprazole. '907 patent at 3:25–38.

The "Background of the Invention" section of the '907 patent criticizes the ability of both H2 blockers and PPIs to provide stomach protection during NSAID use ('907 patent at 1:40–2:12), and specifically notes that PPIs' "antisecretory effect [on stomach acid] may be delayed by several hours and may not take effect for several days." '907 patent at 1:59–64. The '907 patent also recognizes that prior art patents combined NSAIDs and PPIs to reduce the gastrointestinal side effects associated with NSAID administration. '907 patent at 2:20–30. Differentiating this prior art from the asserted invention, the '907 patent notes that this prior art "do[es] not provide for coordinated drug release or for reducing intragastric acid levels to a non-toxic level prior to release of NSAID." '907 patent at 2:24–27. This same section criticizes certain prior art because it "would expose the gastrointestinal tract to NSAIDs prior to onset of PPI activity." '907 patent at 2:29–30.

1. "wherein said unit dosage form provides for coordinated release"[3]

Claim(s)	Plaintiffs' Construction	Anchen's Construction
5, 15, 52–54	wherein the single entity for drug administration provides for the sequential release of acid inhibitor followed by NSAID	release of the NSAID in the unit dosage form is prevented until the acid inhibitor in the unit dosage form increases gastric pH [to at least 3.5][4]

Claim 1 requires that the "unit dosage form provides for coordinated release" of the acid inhibitor and the NSAID. The specification of the '907 patent makes it abundantly clear that the release of the NSAID in the unit dosage form does not occur until the acid inhibitor in that same

[3] DRL and Lupin did not seek construction of this term.

[4] The "to at least 3.5" language in Anchen's construction is included simply to provide context for the language found earlier in the claim, i.e. "an acid inhibitor present in an amount effective to raise the gastric pH of said patient *to at least 3.5*" (emphasis added). The "to at least 3.5" language is not itself in dispute and does not itself form a part of Anchen's proposed construction for the phrase "wherein said unit dosage form provides for coordinated release."

unit dosage form has raised gastric pH. The prosecution history also supports this notion. Since Anchen's construction is consistent with the specification and the prosecution history, it should be adopted.

One need look no further than the "Field of the Invention" and "Abstract" sections of the specification to understand that "coordinated release" of acid inhibitor and NSAID is fundamental to the patentee's contemplated invention:

> The present invention is directed to pharmaceutical compositions that provide for the coordinated release of an acid inhibitor and a non-steroidal anti-inflammatory drug (NSAID). These compositions have a reduced likelihood of causing unwanted side effects, especially gastrointestinal side effects, when administered as a treatment for pain, arthritis and other conditions amenable to treatment with NSAIDs.

'907 patent at 1:11–14.

The dosage form of the asserted invention is "designed so that the NSAID is not released *until* the intragastric pH has been raised to a safe level." '907 patent Abstract (emphasis added). Indeed, the patentee criticized the prior art as lacking this supposed benefit. '907 patent at 2:24–30 (criticizing prior art because it does not "reduc[e] intragastric acid levels to a non-toxic level *prior to release of NSAID*" and "would expose the gastrointestinal tract to NSAIDs *prior to onset of PPI activity*" (emphasis added)). Given the '907 patent's emphasis of this feature, Plaintiffs cannot now argue for a construction that improperly omits it. *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1333 (Fed. Cir. 2009) ("Where the general summary or description of the invention describes a feature of the invention . . . and criticizes other products . . . that lack that same feature, this operates as a clear disavowal of these other products . . . .") (quoting *Astrazeneca AB v. Mut. Pharm. Co.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004)); *see also Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1324 (Fed. Cir. 2008) (The specification "is always highly relevant to the claim construction analysis. Usually, it is

dispositive; it is the single best guide to the meaning of a disputed term." (quoting *Phillips*, 415 F.3d at 1315)).

The specification of the '907 patent also teaches that "[a] unit dosage form of the present invention preferably provides for coordinated drug release, *in a way that elevates gastric pH* and reduces the deleterious effects of the NSAID on the gastroduodenal mucosa, i.e., the acid inhibitor is released first and the release of NSAID is delayed *until after the pH in the GI tract has risen*." '907 patent at 3:62–4:2 (emphasis added). In describing the types of polymer coatings that could be used to delay the release of NSAID, the '907 patent teaches that the function of one such coating "is to prevent the release of [NSAID] *until the pH of the stomach rises*." '907 patent at 10:61–62. It is thus clear from the specification that in order to have "coordinated release" according to the '907 patent, NSAID release from the dosage form must be prevented until the acid inhibitor in the unit dosage form increases gastric pH.

Anchen's construction is also supported by the prosecution history. In differentiating the asserted invention from prior art during prosecution of the '907 patent, the patentee argued that "claim 1 requires that there be a single unit dosage form containing both an acid inhibitor and an NSAID and that, *upon administration to a patient, the dosage form deliver these drugs in a coordinated fashion* such that the acid inhibitor is released first and the *NSAID is not released until after the gastric pH of the patient is 3.5 or higher*." Response dated July 22, 2004 at 3 (emphasis added). In the same response, the patentee differentiated the asserted invention from other prior art by arguing that the reference "fails to disclose dosage forms or procedures in which an acid inhibitor is used for the purpose of raising the pH of the gastrointestinal tract of a patient and which is *combined with an NSAID that is only released after this pH rises above 3.5*." Response dated July 22, 2004 at 5 (emphasis added). The import of these statements is

unmistakable: "*the*" unit dosage form delivers the acid inhibitor and the NSAID in a coordinated fashion, meaning that the acid inhibitor in *that* unit dosage form is released first and the NSAID is not released until after the acid inhibitor in *that* unit dosage form has raised "*this*" gastric pH to at least 3.5. These statements show the patentee's intent that the acid inhibitor in the unit dosage form must raise gastric pH at the time it is administered, and that release of the NSAID *in that same unit dosage form* is delayed until after this pH rises.

Plaintiffs' proposed construction seeks to make "coordinated release" read "sequential release," i.e., release of one drug followed by the other. For support, Plaintiffs rely on the thinnest of evidence: a single mention of the word "sequential" in the specification. *See* '907 patent at 5:16–20. This excessively simplistic construction is belied by the overwhelming weight of the other sections of the specification and prosecution history clearly indicating that "coordinated release" means something more than simply releasing one drug then another. Indeed, the prosecution history shows that Plaintiffs' proposed construction cannot be correct because the patentee amended claim 1 from "coordinated release of said acid inhibitor followed by said NSAID" to "coordinated release such that said acid inhibitor is released first and said NSAID is not released until the gastric pH of said patient is 3.5 or higher." Preliminary Amendment dated October 17, 2003 at 3. This amendment shows that "coordinated release" cannot mean "sequential release of acid inhibitor followed by NSAID" as proposed by Plaintiffs because this same terminology was changed during prosecution.

Plaintiffs' attempt to equate "coordinated" with "sequential" ignores the fact that the claim term is the former rather than the latter; if the patentee had meant to claim "sequential" release then it simply could have said that. To the contrary, "coordinated" means more than Plaintiffs' overly simplified construction. Here it must mean that effect of the acid inhibitor on

gastric pH must take place before the release of the NSAID. It is not the mere *release* of the acid inhibitor that must occur before the NSAID is released; rather, it is the *effect* of the acid inhibitor (i.e., the increase of gastric pH) that must first take place. The '907 patent does not permit any other construction.

Anchen's construction preserves this meaning and so should be adopted.

2. "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon administration of one or more of said unit dosage forms"[5]

Claim(s)	Plaintiffs' Construction	Anchen's Construction
5, 15, 52–54	an acid inhibitor present in an amount capable of raising the gastric pH of said patient to at least 3.5 upon the administration of one or more single entities for drug administration over a period of time.	an acid inhibitor is present in the unit dosage form in an amount effective to raise gastric pH to at least 3.5 at the time the unit dosage form is administered

Claim 1 requires "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon administration of one or more of said unit dosage forms." Construction of this term is related to the construction of the term "wherein said unit dosage form provides for coordinated release," as discussed above. Because claim 1 requires coordinated release of the acid inhibitor and the NSAID, the acid inhibitor must be present in the unit dosage form in an amount effective to raise gastric pH to at least 3.5 *at the time the unit dosage form is administered*. Since Anchen's construction is consistent with the other terms in claim 1, the specification, and the prosecution history, it should be adopted.

As noted above, one of the fundamental aspects of the '907 patent is a dosage form "designed so that the NSAID is not released *until* the intragastric pH has been raised to a safe level." '907 patent Abstract (emphasis added). What raises the intragastric pH is the acid

[5] DRL and Lupin did not seek construction of this term.

inhibitor in *that* unit dosage form. Without the "one-two punch" of (1) release of the acid inhibitor in the unit dosage form to cause a rise in gastric pH, (2) followed by release of the NSAID in *that* unit dosage form, there is no "coordinated" release; the asserted invention would not provide any gastric protection prior to NSAID release, thus defeating the fundamental concept of the asserted invention.[6] The '907 patent's teaching that, in the unit dosage form "the acid inhibitor is released first and the *release of NSAID is delayed until after the pH in the GI tract has risen*" ('907 patent at 3:67–4:2 (emphasis added)), evidences the patentees' intention that the acid inhibitor first increases pH and thereafter *that* dosage form releases the NSAID.

The prosecution history also supports Anchen's construction. As noted above, in arguing over the prior art, the patentee noted that "claim 1 requires that there be a single unit dosage form containing both an acid inhibitor and an NSAID and that, *upon administration to a patient, the dosage form deliver these drugs in a coordinated fashion such that the acid inhibitor is released first and the NSAID is not released until after the gastric pH of the patient is 3.5 or higher*." Response dated July 22, 2004 at 3 (emphasis added). The patentee was unequivocal that "upon" administration of the unit dosage form, i.e., at the time the unit dosage form is administered,[7] the acid inhibitor raises the gastric pH to 3.5 or higher, and the NSAID is not released until after this event occurs. Thus, the acid inhibitor must be present in the unit dosage form in an amount effective to raise gastric pH to at least 3.5 *at the time* the unit dosage form is administered.

Plaintiffs' proffered construction improperly shifts the requirement as to when the acid inhibitor is effective from at the time of administration to the undefined "over a period

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[6] Declaration of Roy Orlando, M.D., in Support of Anchen's Opening Claim Construction Brief, ¶ 23 (Ex. 1).

[7] *See, e.g.*, THE CONCISE OXFORD ENGLISH DICTIONARY OF CURRENT ENGLISH (Della Thompson ed., 9th ed. 1995), "upon" at 1542 ("/əˈpɒn/ *prep.* = ON."); "on" at 950 ("/ɒn/ *prep., adv. & n.* • *prep.* . . . **3** (of time) exactly at; during; contemporaneously with . . . ; **4** immediately after or before . . . .") (Ex. 2).

of time." But the '907 patent does not provide any indication of how long such a "period of time" may be. The very vagueness of Plaintiff's proposed construction is sufficient in and of itself to disqualify it from consideration. The construction's disregard for other claim terminology, the specification, and the prosecution history demonstrates it to be doubly inappropriate. Anchen's construction does not seek to define the disputed claim term in an improperly ambiguous manner and is true to the intrinsic evidence. Thus, Anchen's construction should be adopted.

3. "a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher"

Claim(s)	Plaintiffs' Construction	Defendants' Construction
5, 15, 52–54	No construction is needed. This phrase should be given its plain and ordinary meaning.	a coating that, upon ingestion of said unit dosage form by said patient, controls the release of NSAID by time or pH and thereby prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher

Anchen adopts the section of the DRL/Lupin Brief addressing the construction of this claim term.

4. "at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5" and "enteric coating"

Claim(s)	Plaintiffs' Construction	Defendants' Construction
5, 15, 52–54	at least a portion of said proton pump inhibitor is immediately released	at least some amount of acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5
5, 15, 52–54	"enteric coating" means a delayed release coating	"enteric coating" means a coating that controls the release of an active agent from a unit dosage form by pH

Anchen adopts the section of the DRL/Lupin Brief addressing the construction of these claim terms.

C. U.S. Patent Nos. 6,369,085, 7,411,070, and 7,745,466

1. "magnesium salt of S-omeprazole trihydrate"

Claim(s)	Plaintiffs' Construction	Defendants' Construction
'466 patent; claims 1–5, 7–14, and 16. '070 patent; claims 1–4. '085 patent; claims 1–4 and 12.	"magnesium salt of" means a compound formed between positively-charged Magnesium (Mg) cations and negatively-charged S-omeprazole anions. "S-omeprazole trihydrate" means (S)-omeprazole having a structure that has a theoretical ratio of three molecules of bound water per molecule of ((S)-omeprazole)2 magnesium, but which does not necessarily contain exactly three molecules of water, whose structure may be determined by analytical methods identified in the patent and known to those of ordinary skill. In the '085 patent the structure is determined by examining XRD.	a trihydrate of a magnesium salt of S-omeprazole containing three molecules of water per molecule of magnesium salt of S-omeprazole in a unit cell of the crystal lattice that is substantially free from magnesium salts of R-omeprazole and other prior art forms of magnesium salts of S-omeprazole including S-omeprazole dihydrate and amorphous forms

Anchen adopts the section of the DRL/Lupin Brief addressing the construction of this claim term.

2. "highly crystalline form"

Claim(s)	Plaintiffs' Construction	Defendants' Construction
'466 patent; claims 4, 12 '085 patent; claims 2-4, and 12.	a form having a repeating pattern of atoms or molecules in an order that can be detected by techniques known in the art, that is more ordered than previously known and disclosed forms.	having a crystallinity higher than any other form of magnesium salt of S-omeprazole disclosed in the prior art

Anchen adopts the section of the DRL/Lupin Brief addressing the construction of this claim term.

3. "characterized by the following major peaks in its X-ray diffractogram"

Claim(s)	Plaintiffs' Construction	Anchen's Construction
'085 patent; 1–4, 12 '466 patent; claims 3, 11	identifiable by reference to an X-ray diffractogram that includes the major peaks below	having all of the referenced major peaks in its X-ray diffractogram

Claim 1 of the '085 patent and claims 3 and 11 of the '466 patent are each directed to "*the* magnesium salt of S-omeprazole trihydrate" (emphasis added) which, in reference to the following table, is "characterized by the following major peaks it its X-ray diffractogram":

d-value / Å	Relative Intensity
2.67	m
2.79	m
3.27	m
3.52	s
3.82	s
3.96	vs
4.14	m
5.2	m
5.6	m
6.7	vs
6.9	s
8.3	w
16.6	vs

.

There is no dispute that the numbers in the left-hand column indicate a position on the x-axis of a peak in an X-ray diffractogram of the material in question and the letters in the right-hand column indicate a relative intensity of the corresponding peak (with "m" meaning "medium, "s" meaning strong, and so on; *see* '085 patent at 5:34–40). Anchen's construction, that the claimed magnesium salt of S-omeprazole trihydrate must have *all* of the referenced major peaks in its X-ray diffractogram, is consistent with the plain claim language. Anchen's construction does not introduce any vague extraneous concepts that themselves need interpretation.

On the other hand, Plaintiffs' proposed construction, "identifiable by reference to an X-ray diffractogram that includes the major peaks below," is inconsistent with the plain claim language and injects new terms such as "identifiable by" that would need interpretation. For example, do Plaintiffs mean that the claimed magnesium salt of S-omeprazole trihydrate need only have *some* of the same peaks as the X-ray diffractogram of the claims and some of the same peaks as another, unidentified X-ray diffractogram? Clearly, the claim language requires that the X-ray diffractogram of the claimed product must include the peaks listed. Plaintiffs' proposed construction fails to capture this essential concept and so must be rejected.

4. "represented by FIG. 1"

Claim(s)	Plaintiffs' Construction	Anchen's Construction
'070 patent; claims 2, 4 '466 patent; claims 2, 10	represented by Figure 1 of the '070 patent (or '466 patent)	having an X-ray powder diffractogram the same as FIG. 1

Claim 2 of the '070 patent and claims 2 and 10 of the '466 patent require that the claimed magnesium salt of S-omeprazole trihydrate "is represented by FIG. 1." This claim language refers to the Figure 1 of the '070 and '466 patents, which is as follows:

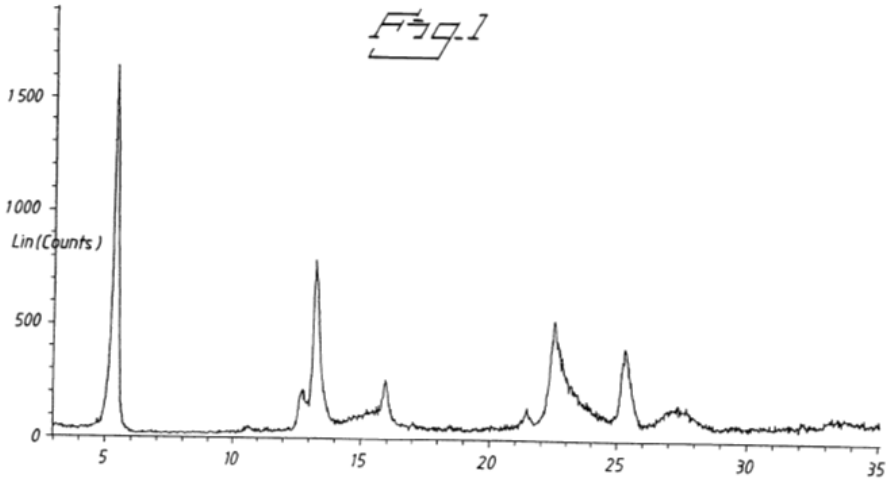

Figure 1 is a graph of position (on the x axis) plotted against intensity (on the y axis), obtained when a powder sample is irradiated with X-rays at various angles indicated by the numbers on the x axis.

Plaintiffs' proposed "construction" merely parrots the language of the claim. Anchen's construction, however, provides the requisite specificity to a very narrow claim. In the context of the '070 and '466 patents, "represented by" *must* mean that the claimed product has an X-ray powder diffractogram that is *the same* as the X-ray powder diffractogram of Figure 1 – there is simply no other construction that has any basis in the patents. Plaintiffs seek to cover a product that could be "represented by FIG. 1" even though it has an X-ray powder diffractogram that is not the same as Figure 1. However, such a construction is unsupportable and obfuscates rather than clarifies the meaning of the term at issue. Plaintiffs' construction must accordingly be rejected.

IV. CONCLUSION

For the foregoing reasons, Anchen respectfully request that this Court adopt the constructions of the disputed terms that have been proposed by Anchen.

DATED: August 30, 2012

Respectfully submitted,

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